Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/NZ04/000315

International filing date: 06 December 2004 (06.12.2004)

Document type: Certified copy of priority document

Document details: Country/Office: NZ
Number: 530060
Filing date: 08 December 2003 (08.12.2003)

Date of receipt at the International Bureau: 17 January 2005 (17.01.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

Ministry of Economic Development
Manatū Ōhanga
Intellectual Property Office of New Zealand

PCT/NZ2004/000315

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 8 December 2003 with an application for Letters Patent number 530060 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 11 January 2005.

Neville Harris
Commissioner of Patents, Trade Marks and Designs

COMMISSIONER OF PATENTS, TRADEMARKS & DESIGNS
NEW ZEALAND

330 High Street, Lower Hutt
PO Box 30687, Lower Hutt, New Zealand or DX SX 11129, Wellington
Freephone: 0508 4 IPONZ (0508 447 669), International callers dial: +64 3 962 2607, Fax: +64 4 560 1691, www.iponz.govt.nz

530060

NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"Breathing Assistance Apparatus"

We, **FISHER & PAYKEL HEALTHCARE LIMITED**, a company duly incorporated under the laws of New Zealand, of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

FIELD OF INVENTION

This invention relates to patient interfaces particularly though not solely for use in delivering CPAP therapy to patients suffering from obstructive sleep apnoea (OSA). In particular, this invention relates to cushions used to support and seal the mask to a patient's face.

BACKGROUND OF THE INVENTION

In the art of respiration devices, there are well known variety of respiratory masks which cover the nose and/or mouth of a human patient in order to provide a continuous seal around the nasal and/or oral areas of the face such that gas may be provided at positive pressure within the mask for consumption by the patient. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

One requisite of such respiratory masks has been that they provide an effective seal against the patient's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the patient. This problem is most crucial in those applications, especially medical applications, which require the patient to wear such a mask continuously for hours or perhaps even days. In such situations, the patient will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable patient discomfort.

US Patent No. 5,243,971 and US Patent No. 6,112,746 are examples of prior art attempts to improve the mask system US Patent No. 5,570,689 and PCT publication No. WO 00/78384 are examples of attempts to improve the forehead rest.

US6,634,358 and US6,581,602 of ResMed Limited disclose a nasal mask cushion to sealingly connect a mask to a wearer's face. The cushion has a nose-receiving cavity bounded by a frame and membrane. The membrane is spaced away from the rim of the frame, and its outer surface is of substantially the same shape as the rim.

In the prior art mask cushions are provided that have a solid inner wall that provides support but doesn't allow much change in the shape of the cushion. Thus such mask cushions can be uncomfortable for a user. Furthermore, often prior art mask cushions are made of foam which is neither waterproof nor durable.

SUMMARY OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface which goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

Accordingly in a first aspect the present invention may be broadly said to consist in a cushion for a patient interface adapted to supply gas to a patient comprising a cushion body; and an outer cover, wherein said body and cover are substantially formed of the same elemental material.

Preferably said elemental material is polyurethane.

Preferably said cushion body is formed in polyurethane foam.

Preferably said outer cover is formed in polyurethane film.

Preferably said outer cover is adhered to said body.

Preferably said cushion body is assembled from more than one moulded component.

Preferably said cushion body includes an attachment adapted to engage a mask.

In a second aspect the present invention may be broadly said to consist in a mask adapted to deliver gas to a patient comprising:

a cushion body wherein at least a portion thereof has a plurality of adjacent voids.

Preferably each void has a hexagonal cross section.

Alternatively each void has an oval, square, rectangular, or other shaped cross section.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred forms of the present invention will now be described with reference to the accompanying drawings.

Figure 1 is a block diagram of a humidified continuous positive airway pressure system as might be used in conjunction with the present invention.

Figure 2 is an illustration of a nasal mask in use with a cushion according to the preferred embodiment of the present invention.

Figure 3 shows a perspective view of the mask with cushion.

Figure 4 is a cutaway view of the mask showing the cushion.

Figure 5 shows a cross section of second preferred embodiment of the mask cushion.

Figure 6 shows perspective view of an inner cushion of the second preferred embodiment of the mask cushion.

Figure 7 shows a cross section of an inner cushion with a reinforcement film or coating.

Figure 8 shows a cross section of an inner cushion made up of two portions welded or glued in the middle.

Figure 9 shows a cross section of an inner cushion with a connecting catch between the halved portions of the cushion.

Figure 10 shows a cross section of a halved foam cushion with mounting brackets.

Figure 11 shows a plan view of a mask cushion having a honeycomb-like structure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides improvements in the delivery of CPAP therapy. In particular a patient interface and cushion is described which is quieter for the patient to wear and reduces leakage from the mask, therefore providing for a good seal on a wearer's nose and face. Furthermore, the patient interface and cushion of the present invention provides for conformity to a patient's facial contours unlike other solid silicone mask or cushion designs and is comfortable for a patient to wear. Also, the cushion of the present invention is durable and allows the pressure of the face of a user to be reduced preventing face sores and the like.

It will be appreciated that the patient interface as described in the preferred embodiment of the present invention can be used in respiratory care generally or with a ventilator but will now be described below with reference to use in a humidified CPAP system. It will also be appreciated that the present invention can be applied to any form of patient interface including, but not limited to, nasal masks, oral masks and mouthpieces.

With reference to Figure 1 a humidified Continuous Positive Airway Pressure (CPAP) system is shown in which a patient 1 is receiving humidified and pressurised gases through a patient interface 2 connected to a humidified gases transportation pathway or inspiratory

conduit 3. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. Inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 which contains a volume of water 6. Inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based controller executing computer software commands stored in associated memory.

Controller 9 receives input from sources such as patient input means or dial 10 through which a patient of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller may also receive input from other sources, for example temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the patient set humidity or temperature value input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface. The water vapour is then passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 which enters the chamber through inlet 16. Exhaled gases from the patient's mouth are passed directly to ambient surroundings in Figure 1.

Blower 15 is provided with variable pressure regulating means or variable speed fan 21 which draws air or other gases through blower inlet 17. The speed of variable speed fan 21 is controlled by electronic controller 18 (or alternatively the function of controller 18 could be carried out by controller 9) in response to inputs from controller 9 and a patient set predetermined required value (preset value) of pressure or fan speed via dial 19.

Nasal Mask

According to a first embodiment of the present invention the patient interface is shown in Figure 2 as a nasal mask. The mask includes a hollow body 100 with an inlet 101 connected

to the inspiratory conduit 3. The mask 2 is positioned around the nose of the patient 1 with the headgear 103 secured around the back of the head of the patient 1. The headgear 103 preferably attaches to a gliding strap or straps 117 by way of connectors 118. The gliding straps 117 allow for the patient to move his head but the mask 2 and more particularly the cushion 104 is not pulled from the patient's face. The restraining force from the headgear 103 on the hollow body 100 and the forehead rest 105 ensures enough compressive force on the mask cushion 104, to provide an effective seal against the patient's face.

The hollow body 100 is constructed of a relatively inflexible material for example, polycarbonate plastic. Such a material would provide the requisite rigidity as well as being transparent and a relatively good insulator. The expiratory gases can be expelled through a valve (not shown) in the mask, a further expiratory conduit (not shown), or any other such method as is known in the art.

Mask Cushion

Referring now to Figures 3 and 4 in particular, the mask cushion 104 is shown in further detail. The cushion 104 is provided around the periphery of the nasal mask hollow body 100 to provide an effective seal onto the face of the patient to prevent leakage. The mask cushion 104 is shaped to approximately follow the contours of a patient's face. The mask cushion 104 will deform when pressure is applied by the headgear (108, see Figure 2) to adapt to the individual contours of any particular patient. In particular, there is an indented section 106 that fits over the bridge of the patient's nose as well as a less indented section 107to seal around the section beneath the nose and above the upper lip.

In Figure 4 we see that the mask cushion 104 is composed of an inner foam cushion 108 covered by an outer sealing sheath 109. The inner cushion 108 is constructed of a resilient material for example polyurethane foam, to distribute the pressure evenly along the seal around the patient's face. The inner cushion 108 is located around the outer periphery 110 of the open face 111 of the hollow body 100. Similarly the outer sheath 109 may be commonly attached at its base 112 to the periphery 110 and loosely covers over the top of the inner cushion 108.

In the preferred embodiment shown in Figure 4 the bottom of the inner cushion 108 fits into a generally triangular cavity 113 in the hollow body 100. The cavity 113 is formed from a flange 114 running mid-way around the interior of the hollow body 100. The outer sheath 109 fits in place over the cushion 108, holding it in place. The sheath 109 is secured by a snap-fit to the periphery 110 of the hollow body. The periphery 110 of the hollow body is shown

including an outer bead 115. The sheath 109 includes a matching bead 116, whereby once it is stretched around the periphery 110, the two beads 115, 116 engage to hold the sheath 109 in place.

Referring now to Figures 5 and 6, a second preferred embodiment of the mask cushion of the present invention is depicted. In this second embodiment, the inner foam cushion 200 includes a raised bridge 201 in the nasal bridge region. Thus the notch in the contacting portion is less pronounced than proceeding embodiments, however as the raised bridge 201 is unsupported it is much more flexible and results in less pressure on the nasal bridge of the patient. The outer sheath 202 contacts the foam cushion 200 throughout the raised bridge 201.

Referring particularly to Figure 6, the foam cushion 200 includes a check contour 203 to follow the cartilage extending from the middle of the nose, and a contoured lip sealing portion 204 to seal between the base of the nose and the upper lip

Honeycomb Cushion

Referring to Figure 11 a further preferred embodiment of the mask cushion is illustrated. The cushion 400 has a honeycomb structure 401. The cushion 400 is shown in Figure 11 with a partial area of an array of hexagonal areas or voids 401. It must be noted that select parts of the cushion could be made in the honeycomb structure, while other areas are fully formed from foam or the like material. In yet other forms, the whole cushion may be formed in this type of honeycomb-like structure.

This type of honeycomb-like structure of the cushion 400 reduces the pressure on the patient's nasal bridge region in use, meaning this cushion 400 is more comfortable to use.

The hexagonal cushion 400 may be formed in a silicon or rubber material and as such is likely to be more flexible, durable and hygienic. The cushion 400 is preferably formed by injection moulding in silicone. Therefore, a mould for use to mould the cushion will have hexagonal or other appropriately shaped uprights that form the voids in the cushion.

The hexagonal cushion 400 may also be coated with an outer film or coating (not shown) by similar methods as are described below. In particular, the outer coating may be formed from silicone.

Film or Coating

A reinforcement film or coating can be applied onto any of the above described cushion's outer surface to reduce the possibility of tearing of the cushion. Such a reinforcement film would likely be made of a resilient material for example polyurethane. The

coating may be applied onto the cushions surface using a variety of methods, for example, injection of a foam cushion onto the pre-made film that lines the cushion mould or adhering a pre-made cushion with a plastic film using processes such as high frequency welding, ultrasonic welding, or gluing. The film or coating could be a plastic film, for example a durable polyurethane film, or a sprayed or painted on plastic or paint coating. Alternatively, the cushion may be dipped in a plastic or paint to coat it.

Referring to Figure 7, a foam cushion 300 with a reinforcement film 301 is illustrated as a whole foam cushion body 302. The foam cushion body 302 includes an upper outer periphery portion 303 and lower hollow fitting portion 304. The outer periphery portion 3 rests against the patient's face in use and the hollow fitting portion 304 attaches to the mask hollow body, for example, 100 in Figure 4 in a manner as described above.

Referring to Figure 7, the reinforcement film or coating 301 for example, a plastic film, can be applied to the outer periphery portion 303 and hollow fitting potion 304 separately usually by injection moulding (or other appropriate methods) each portion. Then later joining together the portions to form the whole cushion 300. These two portions 303, 304 can be joined using different methods; one example is by high frequency welding where high or ultrasonic frequencies cause the cushion material, for example, foam in the preferred embodiment, to meld together. The advantage of moulding two portions and joining them to make up the cushion is that the cushion is easier to manufacture.

The two portions 303, 304 of the foam cushion 300 are formed by injecting foam into female moulds, then removing these and covering them with a plastic coating then using high or ultrasonic welding to meld the two portions plastic coatings together.

In other forms the cushion 300 may be welded on to the mask hollow body 100. In this form the cushion would be permanently attached to the mask body 100. Here, it is likely that the mask body 100 is made from an injection moulding grade thermoplastic. A film 301 can be applied to the pre-made portions 303, 304 or whole cushion 300 itself. For example, the reinforcement film or coating may be applied on the pre-made cushion 300 by means of spraying (using an air-gun or the like), dipping or painting (of the mould before injecting of the silicone or foam cushion). Again, here the cushion could be made in a single mould or in portions as described above.

In another form the film may be made of durable polyurethane and be vacuum formed onto a female mould, the mould may be a single cavity or multi-cavity to enable multiple forming of

upper and lower portions of the cushion. Foam or other appropriate materials that could be used to make the cushion from is then injected into the cavity onto the film. The foam and film are then left to cure at a temperature between 40°C and 50°C for 5 to 8 minutes. During this time the foam adheres to the film. The end result is a cushion covered with a plastic coating that will be resistant to wear, tear and moisture. Figure 8, shows a cross section of a cushion 500 made up of two portions 501, 502 that are each covered in a coating or film 503 (similar to those described above) that have been welded together where the portions 501, 502 meet.

Referring to Figure 9, the halved portions 601, 602 of the cushion 600 may be formed with a catch or key 604. The two parts of the catch 604 are keyed together to assist in the alignment of the portions 601, 602 and then the portions are welded together. Each of the portions 601, 602 is shown in Figure 9 as being covered by a coating or film 603. The catch of key 604 has the purpose of assisting to align the two portions and to prevent movement of the two portions during welding.

Referring to Figure 10, the cushion 700 may be attached to the mask body with a mounting bracket 701 that clips to a groove (not shown) in the hollow mask body. The cushion 703, for example, moulded of foam, is preferably directly molded on the bracket 701. The reinforcement film or coating 702 is then adhered to the cushion's surface using an adhesive material or high frequency or ultrasonic welding. In alternative forms of the cushion the cushion could be moulded onto the film and then welded to the bracket. The bracket is preferably made from a polyurethane or thermoplastic and has the purpose of enabling the clipping of the cushion to the mask body.

A mask cushion with a film coating will mean that while the cushion remains flexible and soft but is more durable. Furthermore, the cushion will be waterproof, as moisture from the patient's skin or caused by surrounding apparatus or therapy the patient is undergoing, is not absorbed by the cushion. Therefore, the cushion will also be more hygienic.

DATED THIS 8th DAY OF December 2003
AJ PARK
PER
AGENTS FOR THE APPLICANT

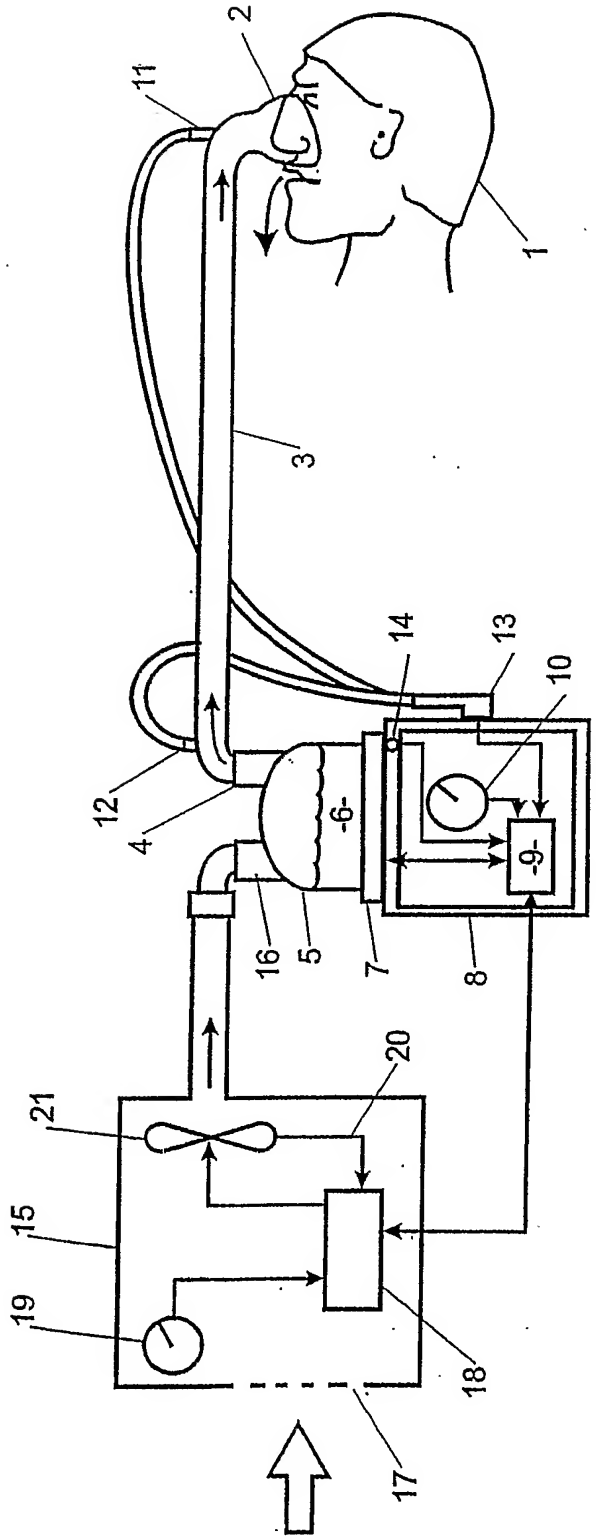

Figure 1

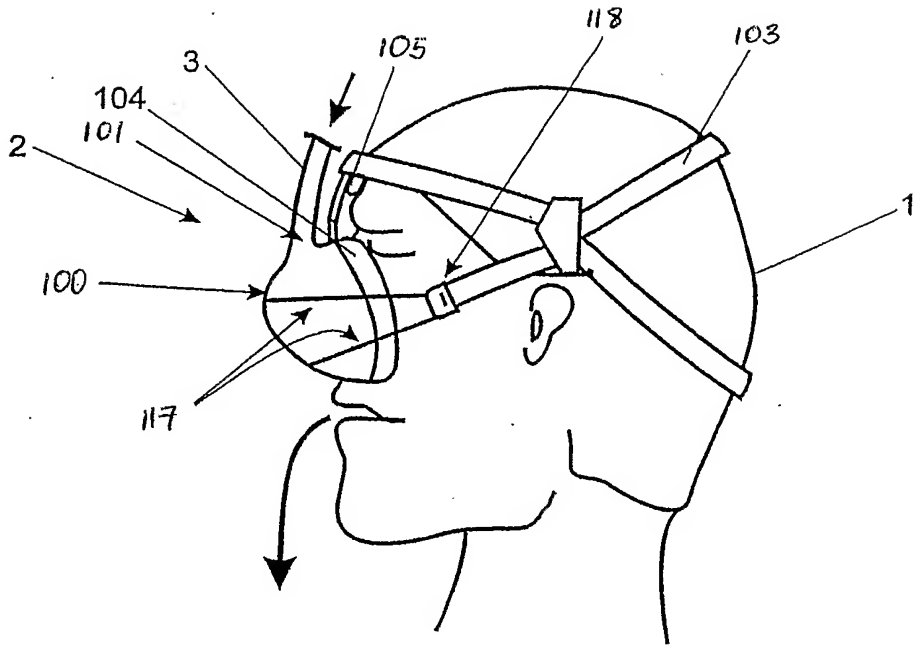

Figure 2

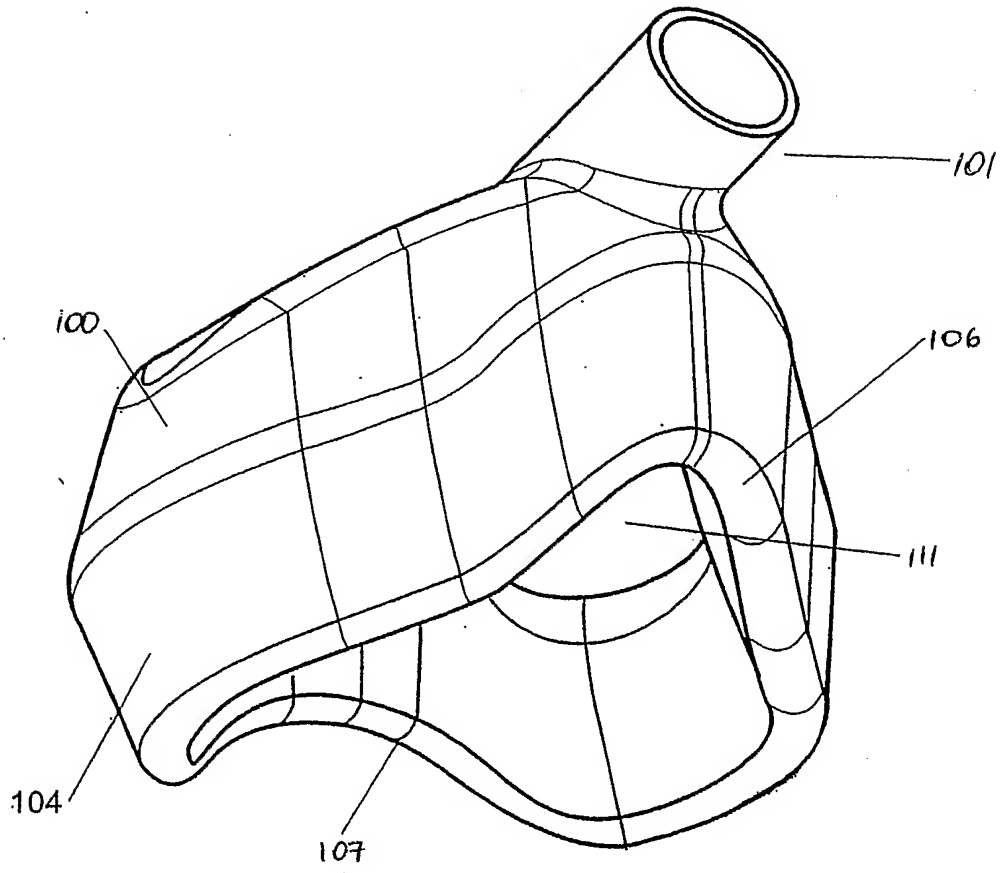

Figure 3

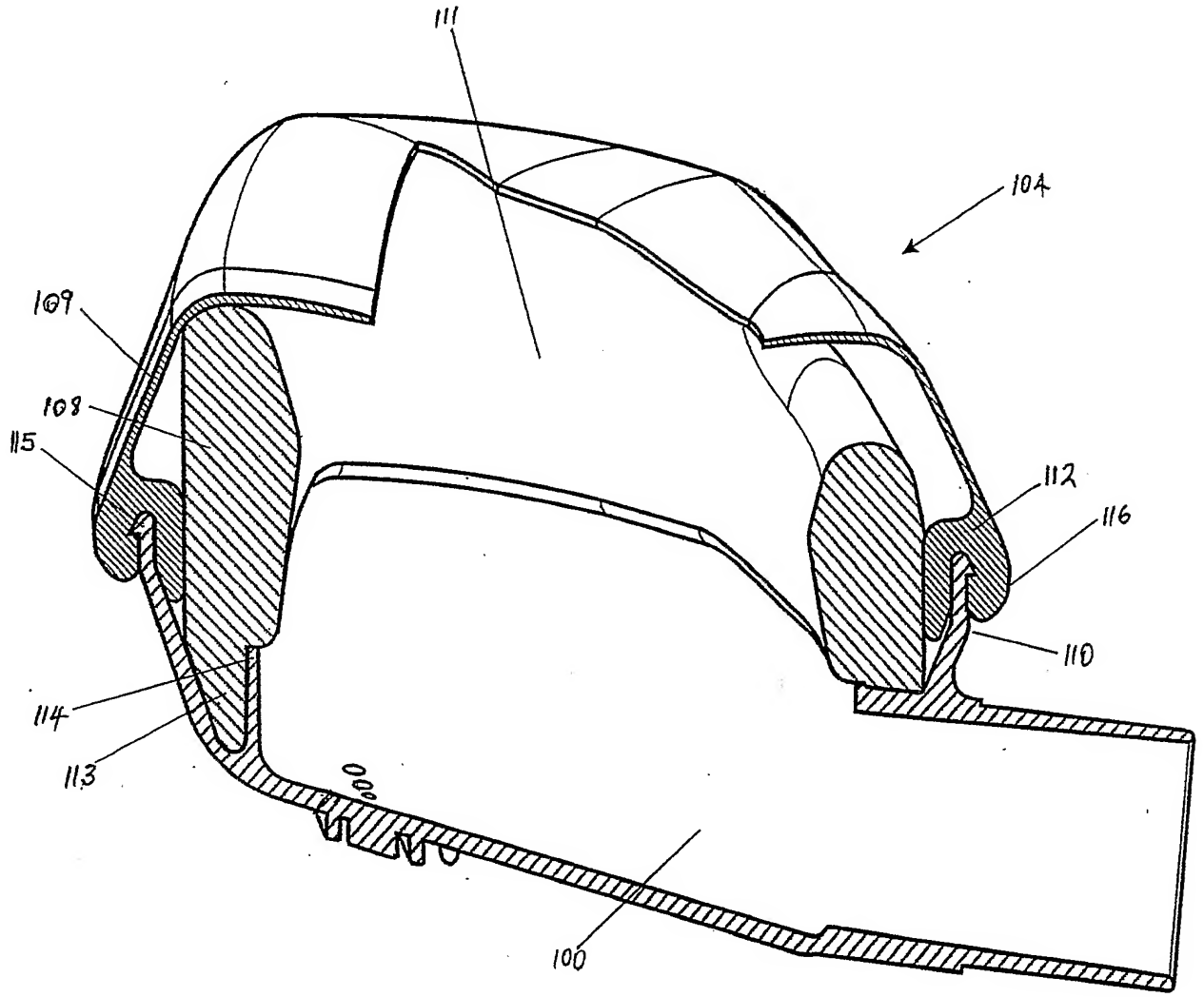

Figure 4

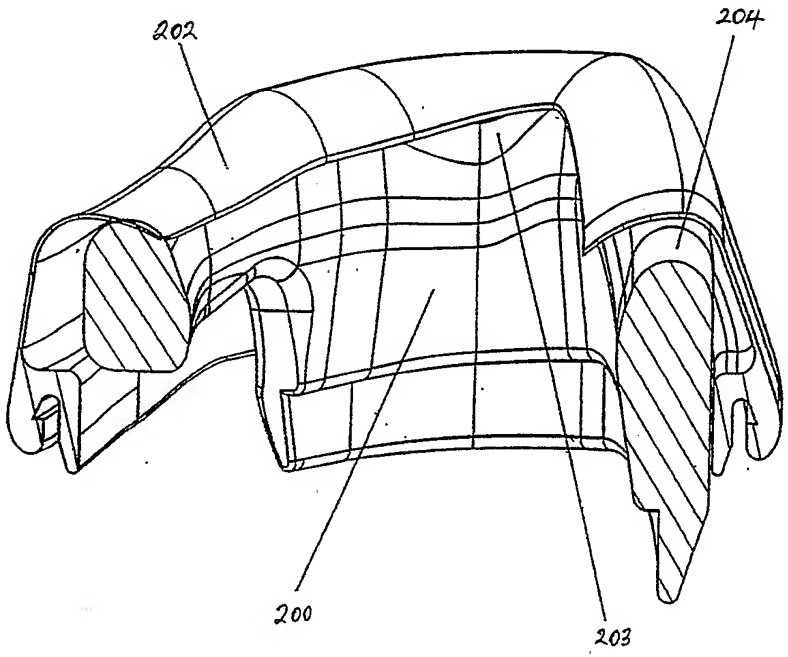

Figure 5

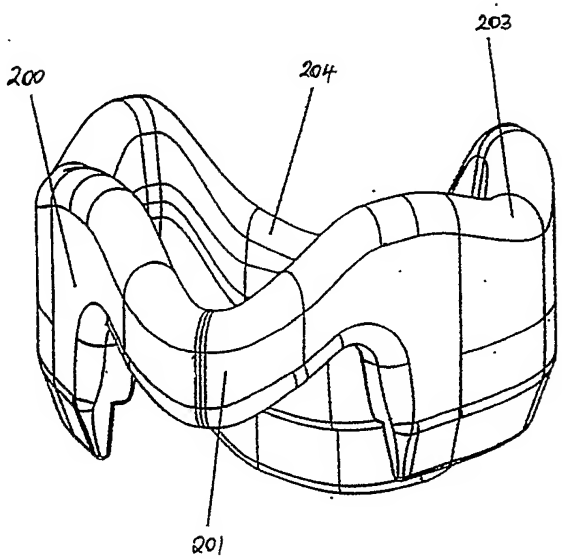

Figure 6

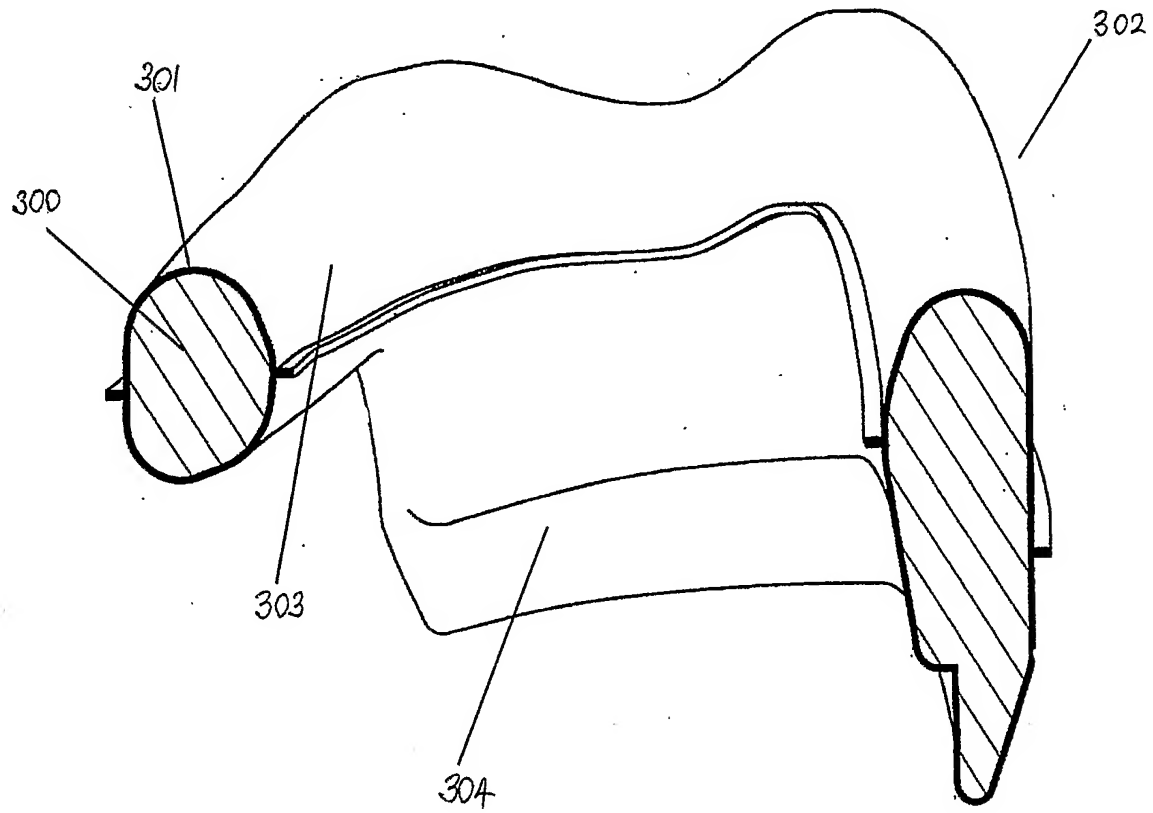

Figure 7

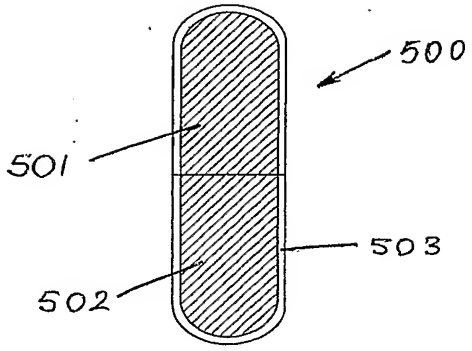

Figure 8

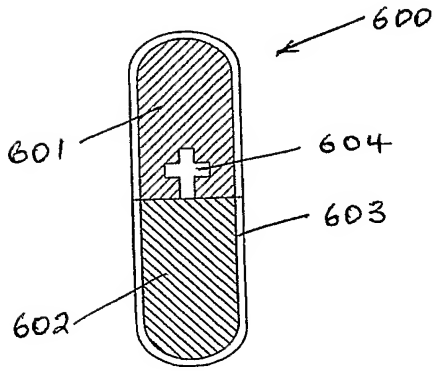

Figure 9

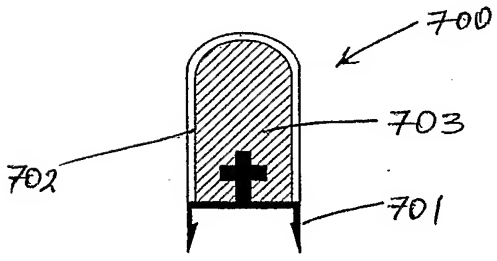

Figure 10

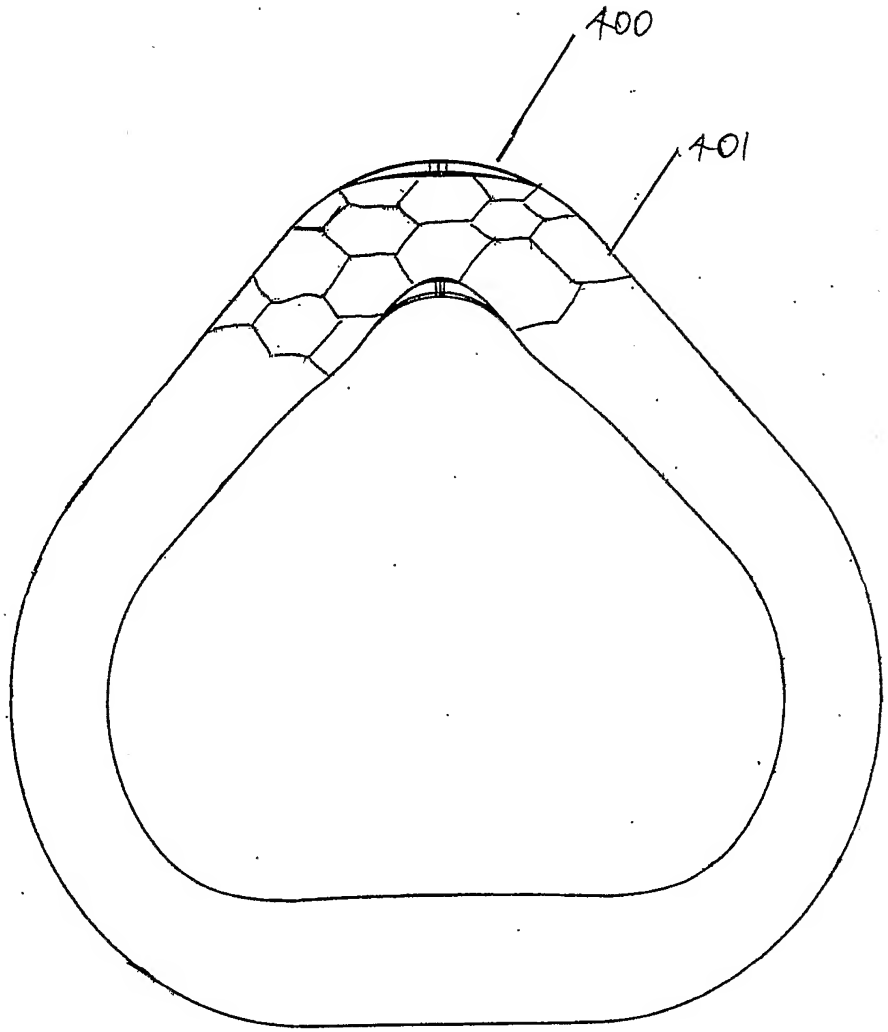

Figure 11